PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Influenza

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

per 0.5 ml

Active substance
Inactivated antigen of one or two strains of Avian Influenza Type A of the following subtypes:
subtype H5N2, strain A/duck/Potsdam/1402/86
subtype H5N6, strain A/duck/Potsdam /2243/84
subtype H7N1, strain A/CK/Italy/473/99
subtype H7N7, strain A/duck/Potsdam/15/80
subtype H9N2, strain A/CK/UAE/415/99
inducing an HI titre of $\geq$6.0 $\log_2$ for each subtype included in the vaccine as tested according to the potency test.

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

250ml
500ml

5. TARGET SPECIES

Chickens and ducks. Other avian species susceptible to avian influenza when considered at particular risk

6. INDICATIONS

For active immunisation of chickens, ducks and other avian species as an aid in the control of outbreaks of avian influenza type A, subtypes H5, H7 and/or H9.
Efficacy has been evaluated on the basis of preliminary results in chickens and ducks. Protection against clinical signs, mortality, and reduction of viral excretion and transmission of virus after challenge were shown by two weeks after vaccination. Protective levels of serum antibody titres would be expected to persist for at least 12 months after administration of two doses of vaccine.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Administer subcutaneously or intramuscularly. A dose of 0.25 to 1.0 ml may be used depending on age and target species, taking into account the following guidance.

Chickens
Vaccinate between 8-10 days of age. Laying hens and breeders should get a second vaccination 6-10 weeks after first vaccination. A dose of 0.5ml is advised but this dose should not be given to chickens aged less than 2 weeks. A dose of 0.25 ml can be used up to an age of 6 weeks. Vaccination of chickens less than two weeks old by the intramuscular route is not recommended.

Ducks
Vaccinate from 14 days of age. Laying and breeder stock should get a second vaccination 6-10 weeks after first vaccination. A dose of 1.0 ml is advised. For ducks up to an age of 6 weeks a dose of 0.5 ml can be used.

Other avian species
Vaccinate as for chickens but a dose of up to 1.0ml, with 0.5 ml for birds up to 6 weeks of age, may be used for some species, e.g. waterfowl.
No information is available on vaccination in the presence of maternally derived antibodies. Immunisation of progeny from vaccinated birds should therefore be delayed until such antibodies have declined.

8. WITHDRAWAL PERIOD

Zero days

9. SPECIAL WARNING(S), IF NECESSARY

This vaccine has been tested for safety in chickens. It may be used in other avian species which are considered at risk of infection but its use in these species should be undertaken with care and it is advisable to test the vaccine on a small number of birds prior to mass vaccination.

The vaccine should be used as part of a co-ordinated disease control programme together with virological monitoring and strict bio-security measures
This vaccine has been evaluated for efficacy in chickens, ducks and turkeys. It may be used in other avian species which are considered at risk of infection where it is expected to provide at least protection against clinical signs and mortality.

To the user:
This product contains mineral oil. Accidental injection/self injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package insert with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

10. EXPIRY DATE

Exp:

11. SPECIAL STORAGE CONDITIONS

Store and transport at 2 to 8°C. Do not freeze.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste material should be disposed of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

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14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd
Walton Manor
Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4625

17. MANUFACTURER'S BATCH NUMBER

BN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Influenza

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

per 0.5 ml

Active substance

Inactivated antigen of one or two strains of Avian Influenza Type A of the following subtypes:
subtype H5N2, strain A/duck/Potsdam/1402/86
subtype H5N6, strain A/duck/Potsdam /2243/84
subtype H7N1, strain A/CK/Italy/473/99
subtype H7N7, strain A/duck/Potsdam/15/80
subtype H9N2, strain A/CK/UAE/415/99
inducing an HI titre of $\geq$6.0 $\log_2$ for each subtype included in the vaccine as tested according to the potency test.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

4. ROUTE(S) OF ADMINISTRATION

Subcutaneous or intramuscular use

5. WITHDRAWAL PERIOD

Zero days

6. BATCH NUMBER

BN:

7. EXPIRY DATE

EXP:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

PACKAGE LEAFLET FOR:

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

MSD Animal Health UK Ltd
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Influenza

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

per 0.5 ml

Active substance
Inactivated antigen of one or two strains of Avian Influenza Type A of the following subtypes:
subtype H5N2, strain A/duck/Potsdam/1402/86
subtype H5N6, strain A/duck/Potsdam /2243/84
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4. INDICATIONS

For active immunisation of chickens, ducks and other avian species as an aid in the control of outbreaks of avian influenza type A, subtypes H5, H7 and/or H9.
Efficacy has been evaluated on the basis of preliminary results in chickens and ducks. Protection against clinical signs, mortality, and reduction of viral excretion and transmission of virus after challenge were shown by two weeks after vaccination. Protective levels of serum antibody titres would be expected to persist for at least 12 months after administration of two doses of vaccine.

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

Safety has been assessed on the basis of preliminary results in chickens and ducks. A transient diffuse swelling may occur at the vaccination site in 50% of the animals.

At the injection site, there may be localised residues of vaccine for a number of weeks after vaccination and occasional signs of inflammation.

7. TARGET SPECIES

Chickens and ducks. Other avian species susceptible to avian influenza when considered at particular risk

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Administer subcutaneously or intramuscularly. A dose of 0.25 to 1.0 ml may be used depending on age and target species, taking into account the following guidance.

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Other avian species
Vaccinate as for chickens but a dose of up to 1.0ml, with 0.5 ml for birds up to 6 weeks of age, may be used for some species, e.g. waterfowl.
No information is available on vaccination in the presence of maternally derived antibodies. Immunisation of progeny from vaccinated birds should therefore be delayed until such antibodies have declined.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Store and transport at 2 to 8°C. Do not freeze.

After broaching use within one working day, providing the product is not subject to extreme temperatures or contaminated.

12. SPECIAL WARNINGS

This vaccine has been tested for safety in chickens. It may be used in other avian species which are considered at risk of infection but its use in these species should be undertaken with care and it is advisable to test the vaccine
e on a small number of birds prior to mass vaccination.

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For Animal Treatment Only

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste material should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2020

15. OTHER INFORMATION

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Vm 01708/4625

Approved 17 November 2020